

# Agricultural Outlook Forum

*Emerging Food Safety Issues in U.S. & Foreign Markets*

## Emerging Strategies for Managing Food Safety

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# **Risk Analysis Process**

- **Risk Assessment**
- **Risk Management**
- **Risk Communication**

# Risk Assessment

- Hazard Identification & Impact
- Hazard Characterization
- Exposure Assessment  
[qualitative and quantitative]
- Risk Characterization

# Risk Management

- **Safe handling procedures and practices, food processing quality and safety assurance controls, food quality and safety standards**

# **A risk management framework is needed to:**

- incorporate scientific information into regulatory and company policies**
- assess the efficacy of measures used to control microbial hazards**

# **Steps for managing microbial hazards**

- 1. Information indicates a need for improved control**
- 2. Conduct a risk evaluation**
- 3. Assess risk management options (ALOP)**
- 4. Establish a food safety objective (FSO)**

- 5. Confirm that the FSO is achievable through GHP and HACCP**
- 6. Establish performance/process/product criteria**
- 7. Establish acceptance procedures:**
  - audits to approve food suppliers**
  - product criteria (e.g., pH,  $a_w$ , microbiological)**

Analytical systematic scientific determinations are preferred.

Emphasis will be placed on the Food Safety Objective (FSO) approach coupled with HACCP that offers a transparent determination in risk management.



**Recently proposed by the International Commission  
on Microbiological Specifications for Foods and on  
its way to acceptance by Codex Alimentarius**

***FSO is a statement of the maximum  
frequency and/or concentration of a  
microbial hazard in a food at the  
time of consumption that provides  
the appropriate level of protection.***

**Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.**

**Processor knows level of hazard considered appropriate in final product and designs process considering initial number of pathogens and any subsequent growth after processing during storage, distribution and preparation.**

**Food Safety Objectives integrate scientific data from risk assessment to designate quantifiable frequencies and concentrations that address specific public health demands.**

**FSO defines expected level of control that must be achieved to meet the appropriate level of consumer protection, considering storage, distribution, sale, and preparation.**

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# Step 1

**Information indicates a need for improved control**

## FoodNet: 1996-2001

	<u>Cases/100,000/year</u>
Listeriosis	0.3 - 0.6
Yersiniosis	0.4 - 1.0
<i>E. coli</i> O157:H7	1.6 - 2.9
Shigellosis	5.0 - 11.6
Salmonellosis, nontyphoid	12.0 - 15.1
Campylobacteriosis	13.8 - 25.2

# Step 2

## Conduct risk evaluation

Examples:

### Quantitative RA

- FDA/USDA and WHO/FAO - *Lm* in RTE foods

### Qualitative RA

- Health Canada - *Salmonella* in cracked eggs
- IFT - *C. botulinum* and *Lm* in cold smoked salmon
- FSIS expert panel - *E. coli* O157:H7 in fermented meats

## **Step 3**

### **Consider risk management options**

- **Consider the level of risk that would be tolerable for the hazard (ALOP)**
- **Identify possible options for controlling the hazard**
- **Select the preferred option(s)**

# **ALOP examples**

**ALOP = 0.0 cases of botulism/100,000/year  
from commercially prepared foods,  
including foodservice**

**ALOP = 0.25 cases of listeriosis/100,000/year**



**Food operators cannot  
effectively respond to an ALOP**

**Regulatory authorities can not  
use an ALOP to evaluate a  
food operation**

## Step 4

### Establish a Food Safety Objective (FSO)

**A statement of the maximum frequency and/or concentration of a microbiological hazard in a food *at the time of consumption* that provides the appropriate level of protection.**

# FSO

- **An outcome of risk evaluation and risk management and intended to:**
  - **limit risk among an exposed population**
  - **inform industry of the expected level of control for food operations.**

- **Serve as a basis for measuring the effectiveness of:**
  - **control systems adopted by industry**
  - **inspection systems adopted by regulatory authorities**
- **Limited to food safety**

**FSO example:**  
***Listeria monocytogenes* in**  
**Ready-To-Eat Foods**

**FSO = *L. monocytogenes* shall not exceed  
100/g or 3.5 log<sub>10</sub> cfu/serving in RTE foods.**

# Achieving an FSO through a PC

**In some cases, the desired level of consumer protection is better achieved through a performance criterion**

# Performance Criterion (PC)

**The expected level of control  
at one or more steps  
*in the food chain.***

# Performance Criteria

$$H_0 - SR + SI \leq FSO$$

**FSO = food safety objective**

**$H_0$  = initial level of the hazard**

**SI = total increase (growth or recontamination)**

**SR = total reduction  
(pathogen inactivation or removal)**



## **FSOs and PC can be used:**

- **as the basis to validate and/or assess the acceptability of a food operation**
- **to force change in an industry to improve food safety**

# **Response to FSOs and PC**

**Industry :**

**establishes control measures  
based upon GHP and HACCP**

**Regulatory authorities :**

**adjust inspection procedures to  
verify the FSOs and/or PC  
are being met**

## **Step 5**

**Confirm that the FSO is achievable  
through GMPs and HACCP**

# Basic Control Measures

## Controlling initial levels

- Avoiding high risk foods (e.g., undercooked ground beef)
- Selecting ingredients from approved sources

## Controlling increase in a hazard

- Preventing contamination (e.g., GMPs)
- Preventing growth of pathogens (e.g., pH,  $a_w$ )

## Reducing a hazard

- Destroying pathogens (e.g., pasteurization)

# HACCP

**The scientific basis for CCPs and critical limits is in:**

- **establishing and validating PC,  
and then**
- **applying appropriate process and/or  
product criteria**

**FSOs and PC can lead to:**

- **process criteria,**
- **product criteria and**
- **default criteria**

# Step 6

## Establish process/product requirements

### Process criteria:

Heating at 71.7C for 15 seconds to  
pasteurize milk

### Product criteria:

pH =  $\leq$  4.6 for high acid canned foods

### Default criteria:

Values stated in regulations or guidelines

## Step 7

### Establish acceptance procedures

#### Finished product specifications:

- chemical
- physical
- organoleptic
- microbiological



# Validation

**Collecting evidence to prove that the control measures are effective and the FSO(s) and/or PC will be met.**

# **Basis for process validation**

- **reports from expert panels**
- **regulations with a scientific basis**
- **scientific literature**
- **laboratory research (e.g., challenge studies)**
- **commercial experience with process and products**

# Validation

**Examples of data collected during production:**

- measurements of time-temperature, pH,  $a_w$
- microbiological data:
  - initial, in-process, final product
- determining process variability and how to minimize



**FSOs and PC are values that must be met; otherwise, they can not be used as a basis for process validation.**

**FSOs and PC are a line in the sand, not target values.**

# $H_0 - SR + SI \neq FSO$

$H_0$ , SR and SI are concentration or frequency distributions, not point values, for the microbial hazard. The distributions are influenced by many factors such as:

- source of the food or ingredients
- pathogen characteristics
- impact of the food on survival/growth
- conditions of processing
- process variability, etc



**Confidence in the safety of a food  
depends  
on the ability of the food industry  
to control variability in  
 $H_o$ , SR and SI throughout the food chain.**

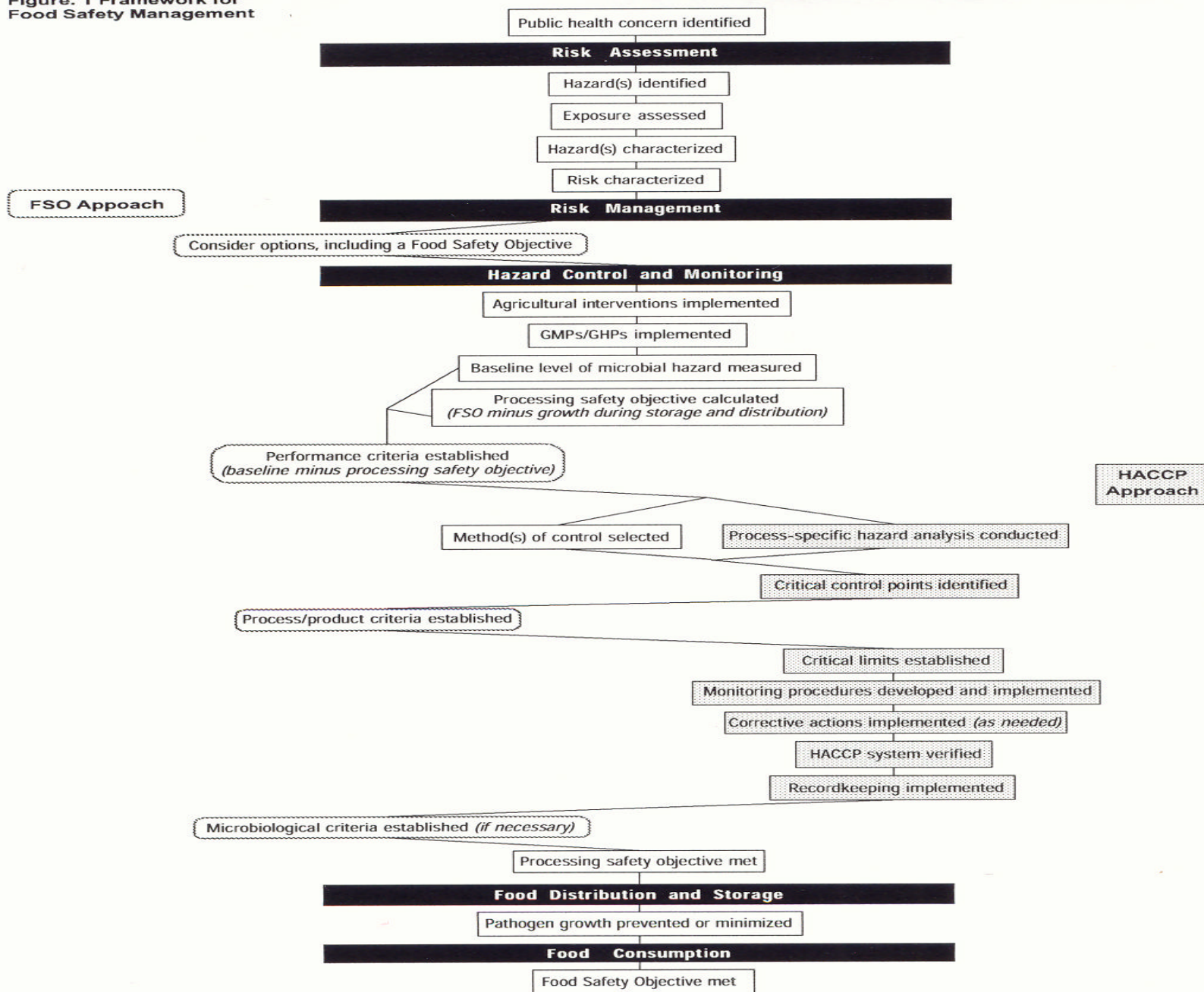
**Variability must be considered  
during process validation to ensure  
safety but also to avoid over-processing.**

*Flowchart of Framework*  
*in*  
**“Emerging Microbiological  
Food Safety Issues”**

published by the  
**Institute of Food Technologists**

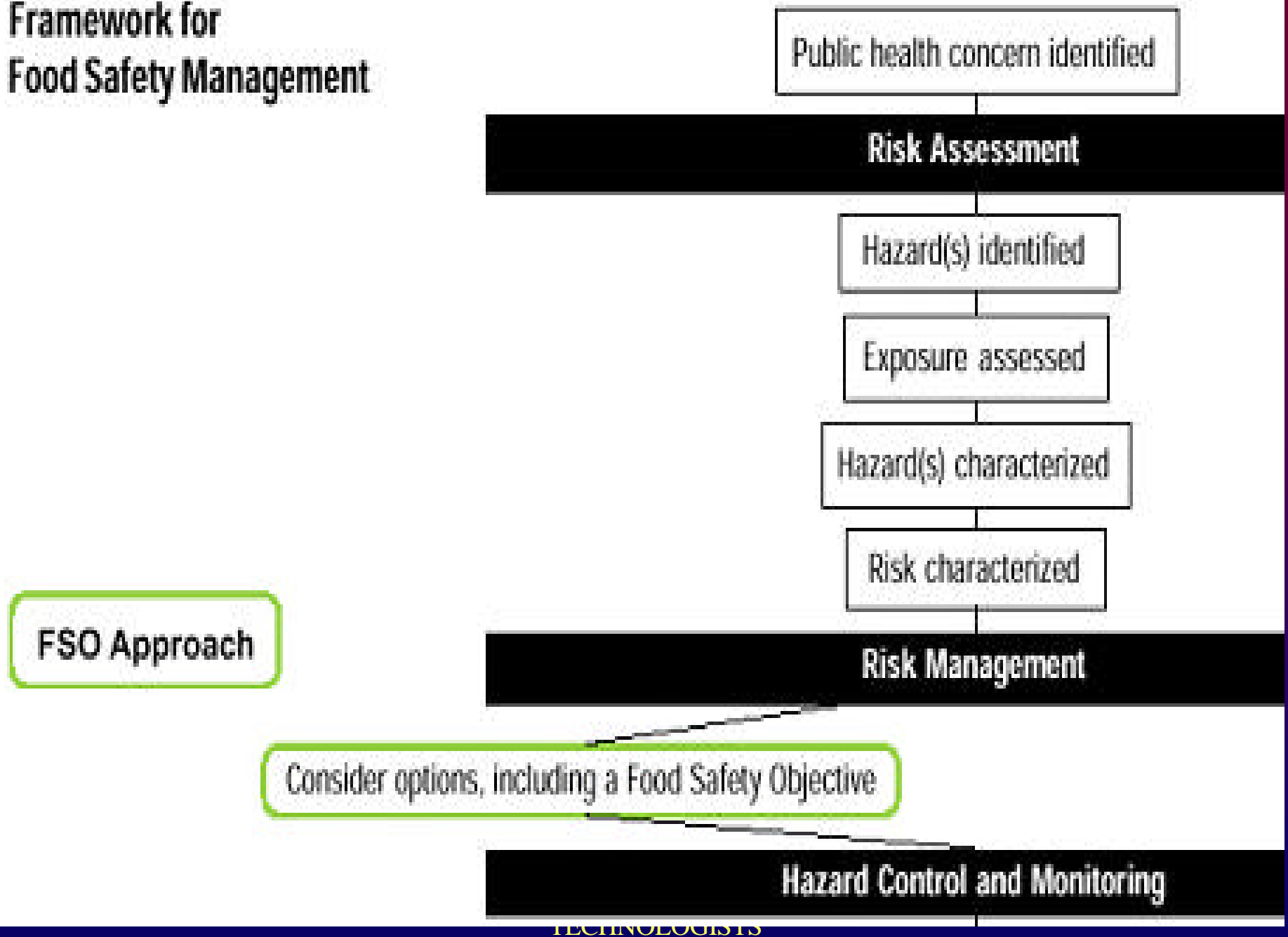
**[www.ift.org](http://www.ift.org)**

**Figure. 1 Framework for Food Safety Management**





# Framework for Food Safety Management



# Hazard Control and Monitoring

Agricultural interventions implemented

GMPs/GHPs implemented

Baseline level of microbial hazard measured

Processing safety objective calculated  
(FSO minus growth during storage and distribution)

Performance criteria established  
(baseline minus processing safety objective)

HACCP  
Approach

Method(s) of control selected

Process-specific hazard analysis conducted

Critical control points identified

Process/product criteria established

Process/product criteria established

Critical limits established

Monitoring procedures developed and implemented

Corrective actions implemented *(as needed)*

HACCP system verified

Recordkeeping implemented

Microbiological criteria established *(if necessary)*

Microbiological criteria established *(if necessary)*

Processing safety objective met

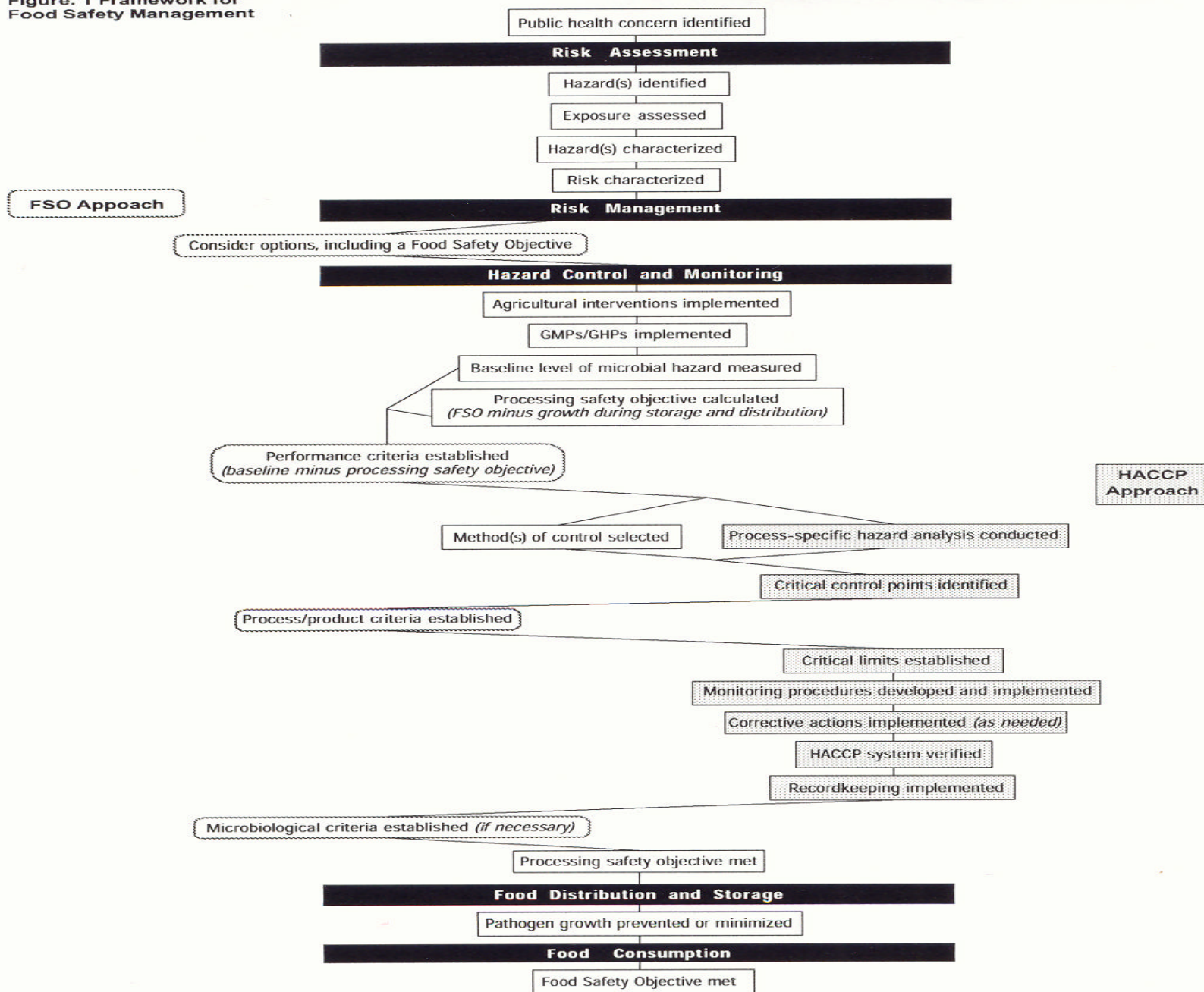
Food Distribution and Storage

Pathogen growth prevented or minimized

Food Consumption

Food Safety Objective met

**Figure. 1 Framework for Food Safety Management**



# Risk Communication

- **provides public with results of expert scientific review of food hazard identification and assessment of risk to general population or target group**
- **provides private and public sectors with information necessary to prevent, reduce, minimize food risks through systems of quality and safety**

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# **This risk management framework**

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